IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

GREGORY W. BARAN , M.D. Plaintiff, v. MEDICAL DEVICE TECHNOLOGIES, INC., et al., Defendant.	)	CASE NO. 1:04cv1251 JUDGE KATHLEEN O'MALLEY

SUPPLEMENTAL EXPERT REPORT OF MAJID RASHIDI, Ph.D., P.E.

Supplementary Report

By

Defendants' Expert: Majid Rashidi, Ph.D., P.E.

Case: Gregory W. Baran, Versus Medical Devices Technologies, Inc., et.al.

BACKGROUND: My Expert Report of February 22, 2008, was based on the analysis of an 18-gauge version of the accused product. My understanding is that Medical Device Technologies, Inc. (Defendant) also produces a 16-gauge version of the accused product, and that product features components that differ slightly from the components of the 18-gauge product that I reviewed. In this report, I examine the 16-gauge product and comment on the modifications that have been made.

The Defendant made minor adjustments to the dimensions of some of the components of the 16-gauge version of the accused product, which appear on the 18-gauge version of the accused product. These adjustments include a change in the angle of the surface under the opening of the Crank Arm that is engaged by the Crank Arm locking tab, illustrated at 28 and 49, respectively, in Figures 1-A through 1-D of my Expert Report. In addition, a Radius on the leading edge of the Slider, illustrated at 46 and 35, respectively, in Figure 1-G of my Expert Report, was changed. Furthermore, the geometry of the stops of Slider, which engage the tabs of the Elongated Release Bar 38 of Figures 1-C through 1-E, was slightly changed. Various other dimensions of the Crank Arm, Slider and Connecting Rod (illustrated at 30 in Figures 1-A, 1-C and 1-D) of the 18-gauge product also vary slightly from their 16-gauge counterparts.

My understanding is that improvements of the manufacturing process and in cocking performance were the motivation behind these minor dimensional adjustments for the 18-gauge version of the accused product. As described in greater detail below, the 16-gauge and 18-gauge versions of the accused product fully adhere to the same principles of operation.

Opinion: It is my opinion, with a high degree of scientific and engineering certainty that:

- The charging/release means of both the 16-gauge and 18-gauge versions of the accused products remain as slider-crank mechanisms even with the above variations in the geometry and dimensions of their components.

- The charging/release mechanism of both the 16-gauge and 18-gauge versions of the accused product is substantially different from the single charging/release member of the device disclosed in claim 7 of '797 patent.

- The **kinematics** principle of operation of the charging/release mechanism of both the 16-gauge and 18-gauge versions of the accused product follows that of a typical slider-crank mechanism. In contrast to both versions of the accused product, the charging/release member of the device disclosed in '797 patent is a single member that its kinematics principle of operation has a trivial sliding motion during its charging phase.

- The **kinetic** principle of operation of the charging/release mechanism of both the 16-gauge and 18-gauge versions of the accused product creates advantageous force amplification features during charging. The device disclosed in claim 7 of '797 patent totally lacks this very important feature. The contrast between the kinetics of both versions of the accused product and the device disclosed in claim 7 of '797 patent has been presented in details in Exhibits 3 and 4 of my Expert Report.

- In both the 16-gauge and 18-gauge versions of the accused product, the stored elastic potential energy of a spring is released by a sliding link that is substantially positioned inside of the device's handle. This sliding link extends to the outside of the device's handle in form of a release button, protruding from the proximal end of the handle. In case of the device disclosed in claim 7 of '797 patent, the release arm is substantially positioned on the outside of its handle. Without a redesign of this so called release arm, the Plaintiff's proposed device may not even release from its charged position upon a release attempt when a person of ordinary skill in the pertinent art makes an effort to practice the teaching of claim 7 of '797 patent.

- I have also observed, under a microscope with 50-times image magnification factor, that the sampling portion of the instrument, located at its distal end, does not function when the instrument is "fired" in the manner (misuse) suggested by the Plaintiff's expert. More specifically, when the charged instrument is fired by prying the crank arm/lever away from the instrument housing, instead of pushing the trigger button as intended, the pincer portion of the outer tube (12 in Figs. 1-A, 1-B and 1-D of my previous report) does not enter the corresponding notch/opening formed in the inner cannula (10 in Fig. 1-D of my previous report). As a result, the biopsy specimen may not be retained in the instrument for removal from the patient. Additionally, the accused product does not have any tab(s) and/or feature(s) that would suggest or encourage the user to fire the device in the manner that the Plaintiff's expert asserts. The intended trigger button of the accused product works inside the handle of the device and its principal of operation does not infringe claim 7 of the '797 patent.

- In both the 16-gauge and 18-gauge versions of the accused product, the Crank Arm, Slider, and Connecting Rod are designed to keep the handle (Crank Arm) fixed to the exterior shell of the accused product when the device is charged . These components are not designed to function or to be used as a release/retainer arrangement of the accused product. As noted on page 35 of my Expert Report, such a use of the accused product would actually be a misuse in a way that is not only unsafe for the patient, but also is against the intended design and performance of the accused product.

Conclusion: Based of the statements I have provided in this supplementary report, I maintain my opinion that both the 16-gauge and 18-gauge versions of the accused products of the Defendants do not infringe claim 7 of U.S. Patent No. 5,025,797.

I do not know either parties of the dispute, and I have no vested interested in the outcome of this dispute.

I further reserve the right to clarify, amend, and supplement my opinions, and to express further opinions, based upon the disclosure of Dr. Baran's experts' opinion and upon development of additional information as this case proceeds to trial.

Dated: September 10, 2008

By: Majid Rashidi

Majid Rashidi, Ph.D., P.E.